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09/962,750 APPLICANT NUMBER	11/03/97 FILING DATE	AUSUBEL FIRST NAMED APPLICANT	160 ATTY. DOCKET NO.
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08/962,750 11/03/97 AUSUBEL

EXAMINER

HM12/1014

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ART. UNIT	PAPER NUMBER
SWARTZ, R	13

DATE MAILED: 1641

10/14/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 23/06/99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-24, 26, 28-45 is/are pending in the application.
Of the above, claim(s) 31-45 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-24, 26, 28-30 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-24, 26, 28-45 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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DETAILED ACTION

1. Applicants' Response to Office Action, received 23 July 1999, paper#12, is acknowledged. Claims 25 and 27 have been canceled without prejudice. Claim 1, 22, 26, and 28 have been amended.
2. Claims 1-24, 26, and 28-45 are pending. Claims 31-45 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention (Office Action, 21 January 1999, paper#10).
3. Currently, claims 1-24, 26, and 28-30 are under consideration.

Rejection Withdrawn/Moot

4. The provisional rejection of claims 1-14, 20-24, 26, and 28-30 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 of copending Application No. 08/852,927 is withdrawn in light of the abandonment of copending Application No. 08/852,927.
5. The provisional rejection of claims 25 and 27 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 of copending Application No. 08/852,927 is moot in light of the cancellation of claims 25 and 27.
6. The rejection of claims 25 and 27 under 35 U.S.C. 112, first paragraph, scope of enablement concerning compounds, is moot in light of the cancellation of claims 25 and 27.

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7. The rejection of claims 25 and 27 under 35 U.S.C. 112, first paragraph, scope of enablement concerning infection/multiplication of Herpes simplex virus in plants, is moot in light of the cancellation of claims 25 and 27.

8. The rejection of claims 25 and 27 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancellation of claims 25 and 27.

9. The rejection of claims 25 and 27 under 35 U.S.C. 103(a) as being unpatentable over Elrod et al (*J. Bacteriol.*, 46:633-645, 1942) or Schroth et al (*Pseudomonas aeruginosa: Ecological Aspects and patient Colonization*, pages 1-29, 1977) in view of Kominos et al (*Appl. Microbiol.*, 24(4):567-570, 1972) and further in view of Geels (*J. Appl. Bacteriol.*, 79:38-42, 1995) and in further in view of Conrad et al (*Rev. Inf. Dis.*, 13, supplement 7:S634-639, 1991) is moot in light of the cancellation of claims 25 and 27.

10. The rejection of claims 1-24, 26, and 28-30 under 35 U.S.C. 112, first paragraph, scope of enablement concerning compounds, is withdrawn in light of the amendments of claim 1 and 22.

11. The rejection of claims 1-24, 26, and 28-30 under 35 U.S.C. 112, first paragraph, scope of enablement concerning infection/multiplication of Herpes simplex virus in plants, is withdrawn in light of the amendments of claim 1 and 22.

12. The rejection of claims 1-24, 26, and 28-30 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendments of claim 1 and 22.

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Rejections Maintained

13. The rejection of claims 1-24, 26, and 28-30 under 35 U.S.C. 103(a) as being unpatentable over Elrod et al (*J. Bacteriol.*, 46:633-645, 1942) or Schroth et al (*Pseudomonas aeruginosa: Ecological Aspects and patient Colonization*, pages 1-29, 1977) in view of Kominos et al (*Appl. Microbiol.*, 24(4):567-570, 1972) and further in view of Geels (*J. Appl. Bacteriol.*, 79:38-42, 1995) and in further in view of Conrad et al (*Rev. Inf. Dis.*, 13, supplement 7:S634-639, 1991) is maintained.

Applicants argue that none of the cited reference combinations teaches or suggests applicants' invention.

Specifically, Elrod et al teach the opposite of what is claimed. While recognizing that the pathogen *P. aeruginosa* is capable of infecting both humans and plants, Elrod et al concluded that such dual pathogenicity resulted from different virulence factors, not common virulence factors as the instant application teaches, and possible from the existence of different strains of the same bacterium.

The examiner has considered applicants' arguments, but does not find them persuasive. The instant claims are directly to a method of identifying compounds which inhibits or reduces pathogenicity of the same pathogen in at least two different eukaryotic organisms, one of which is a non-rodent. The claims are not directed to identifying common or different virulence factors, therefore applicants' argument concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed.

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Elrod et al teach that: 1) “From the results of the biochemical and serological tests it is evident that the two isolates of *P. polycolor* are indistinguishable from certain strains of *P. aeruginosa*.”(page 641, first sentence of *Discussion*); 2) “From the above facts it would be impossible to separate *P. polycolor* from *P. aeruginosa*, and we conclude that the two are identical.” (Page 641, last sentence to page 642, line 2); and 3) “The ability of *P. aeruginosa* to thrive in plant tissues as well as in warm-blooded animals makes it unique in the field of bacteriology.” (Page 643, last sentence of *Summary*). Therefore, Elrod et al teach the same pathogen in plants and animals.

Applicants argue that Schroth et al, like Elrod et al, fails to recognize that dual pathogenicity results from common virulence factors, and absent this recognition this reference is incapable of providing a logical basis for suggesting that effective inhibitory compounds for treating or preventing a pathogen infection in one eukaryotic organism might be identified by screening for those compounds in an entirely different eukaryotic organism.

The examiner has considered applicants’ argument, but does not find it persuasive. As stated in the examiner’s discussion of the Elrod et al arguments, because the claims are not directed to identifying common or different virulence factors, applicants’ argument concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed.

Applicants argue that Schroth et al do not teach that the same strain of *Pseudomonas* is responsible for both infections, and that in view of Elrod et al, one skilled in the art would be led

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to believe that these infections were caused by different strains, one specific for human patients and the other specific for agricultural plants. The examiner has considered applicants' argument, but does not find it persuasive. Schroth et al teach that *Pseudomonas aeruginosa* infects patients in hospitals as well as agricultural plants (page 1, first paragraph; Table 1; section **Pathogenicity of *P. aeruginosa* in Plants**, page 16-22), and does not teach or suggest different strains. As stated above, Elrod et al teach that "The ability of *P. aeruginosa* to thrive in plant tissues as well as in warm-blooded animals makes it unique in the field of bacteriology." (Page 643, last sentence of *Summary*). Therefore, contrary to applicants' belief, one skilled in the art may very well conclude that these infections were caused by identical organisms.

Applicants argue that Kominos et al never teaches or suggests that a single pathogen possesses common virulence factors that render it pathogenic on multiple host organisms, much less that nematodes and plants may be used together to identify compounds that inhibit or reduce the pathogenicity of a pathogen. The examiner has considered applicants' argument, but does not find it persuasive. Applicants' argument concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed. Kominos et al is utilized only for their teaching that plants are an important source and vehicle by which *P. aeruginosa* colonizes the intestinal tract of patients, not for teaching any screening methods.

Applicants argue that Conrad et al never teaches or suggests that a single pathogen possesses common virulence factors that render it pathogenic on multiple host organisms, much

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less that nematodes and plants may be used together to identify compounds that inhibit or reduce the pathogenicity of a pathogen. The examiner has considered applicants' argument, but does not find it persuasive. Applicants' argument concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed.

Applicants argue that Conrad et al only teaches the efficacy of one particular compound to treat *P. aeruginosa* skeletal infections in humans, and never mentions screening systems apart from the described skeletal system might be used to evaluate the efficacy of aztreonam. The examiner has considered applicants' argument, but does not find it persuasive. Conrad et al is cited as a method of testing a suspected compound for treatment of *P. aeruginosa* infection in humans.

Applicants argue that Geels does not teach a plant model to identify compounds that are efficacious for treating a plant pathogen and does not teach any method of using two different eukaryotic organisms to identify compounds that inhibit or reduce the pathogenicity of the same pathogen. The examiner has considered applicants' argument, but does not find it persuasive. Webster's II, New Riverside University Dictionary **defines mushroom as** "Any of various fleshy **fungi** of the class Basidiomycetes" and **fungus as** "Any of numerous **plants** of the division or subkingdom Thallophyta". Therefore, Geels teaches a plant model testing a suspected compound for treatment of *Pseudomonas*.

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Thus, the cited references teach that *Pseudomonas* is a pathogen frequently involved in disease in both plants and animals. Because of this, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to test drug efficacy of a variety of suspected compounds for controlling or eradicating the presence of *Pseudomonas* in both plants and animals. In addition, it would have been obvious to utilize models of both plants and animals in order to identify such compounds.

Conclusion

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

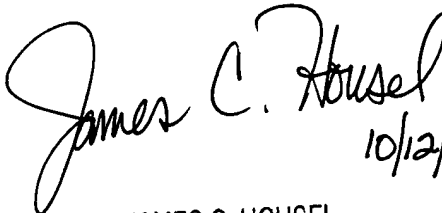
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

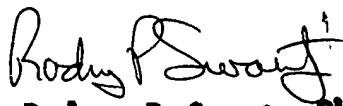
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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703)308-4027. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER


Rodney P. Swartz, Ph. D.
PATENT EXAMINER

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October 7, 1999